May 8, 2018

Hologic, Inc.
Anne-Marie Keefe
Senior Regulatory Affairs Specialist
250 Campus Drive
Marlborough, Massachusetts 01752

Re: K173901
Trade/Device Name: MyoSure MANUAL Tissue Removal Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: April 2, 2018
Received: April 3, 2018

Dear Anne-Marie Keefe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173901

Device Name
MyoSure MANUAL Tissue Removal Device

Indications for Use *(Describe)*
The MyoSure MANUAL Tissue Removal Device is intended for intrauterine use by a trained gynecologist to hysteroscopically resect and remove tissue, including focal lesions such as endometrial polyps and retained products of conception.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K173901

**510(K) SUMMARY**

**Date:** May 7, 2018

**510(k) Submitter:**

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Anne-Marie Keefe
508.263.8851
F: 866.523.8663

**Establishment Registration Number:** 1222780

**Trade Name:** MyoSure MANUAL Tissue Removal Device

**Common/Usual Name:** Hysteroscopic Tissue Removal Device

**Regulation Name:** Hysteroscope and Accessories

**Regulation Number:** 21.CFR.Reg 884.1690

**Product Code**: HIH, Hysteroscope and Accessories

**Classification:** Class II

**Panel:** Obstetrics/Gynecology

**PREDICATE DEVICES**

**Tradename:** MyoSure LITE Tissue Removal Device
**Submitter/510(k) Holder:** Hologic, Inc.
**510(k) #:** K142029
**Product Code**: HIH
**Regulation**: 21.CFR.884.1690

The MyoSure LITE Tissue Removal Device has not been subject to a design-related recall.

**DEVICE DESCRIPTION**

The MyoSure MANUAL Tissue Removal Device is a single-use device that is intended for the resection and removal of tissue under hysteroscopic visualization. It is sterile, non-powered, and hand-actuated. It is compatible with the MyoSure hysteroscope and can be used in either an office or an operating room setting.

The MyoSure MANUAL Tissue Removal Device is packaged with an accessory inflow tube to facilitate delivery of distention media. The inflow tube contains a bag spike, a tube and a luer connection to the hysteroscope.

The MyoSure MANUAL Tissue Removal Device incorporates a rotating outer tube with a side facing cutting window and inner reciprocating cutting blade. A removable in-line tissue trap collects the excised tissue. An Outflow tube transfers and directs the waste fluid into a buttock drape.

**INDICATIONS FOR USE:**

The MyoSure MANUAL Tissue Removal Device is intended for intrauterine use by a trained gynecologist to hysteroscopically resect and remove tissue, including focal lesions such as endometrial polyps and retained products of conception.

The MyoSure MANUAL Tissue Removal Device indications for use are similar to the predicate MyoSure LITE device. The primary difference between the subject MyoSure MANUAL Tissue Removal Device and the predicate MyoSure LITE is as follows:

- Resection and removal of tissue for the MyoSure MANUAL device includes focal lesions such as endometrial polyps and retained products of conception. Resection and removal of tissue for the MyoSure LITE includes submucous myomas. Both the MyoSure MANUAL and MyoSure LITE devices are intended for removal of endometrial polyps and retained products of conception.

The MyoSure MANUAL Tissue Removal Device intended use is identical to the predicate MyoSure LITE device.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:**

Primary specifications including morcellator dimensions (including OD, cutting window and cutting depth) cutting blade configuration, fluid distention media, visualization and access route to targeted tissue are identical to the predicate MyoSure LITE device.

The mode of operation including method of use and mechanism of action, material composition, and aspiration pressure are similar to the predicate MyoSure LITE device.

The primary difference between the subject MyoSure MANUAL Tissue Removal Device and the predicate MyoSure LITE is as follows:

- The MyoSure MANUAL Tissue Removal Device is a hand actuated device while the predicate MyoSure LITE is motor actuated.
- The MyoSure MANUAL Tissue Removal Device consists of a rotatable outer sheath while the MyoSure LITE consists of a stationary outer sheath.
- The MyoSure MANUAL Tissue Removal Device contains an Inflow Tube Assembly while the MyoSure LITE is not packaged with this assembly.
- The MyoSure LITE requires an external vacuum source while the MyoSure MANUAL Tissue Removal Device does not.

The differences in technological characteristics do not raise different questions of safety and effectiveness.

**PERFORMANCE TESTING**

Performance verification and validation testing of the MyoSure MANUAL Tissue Removal Device evaluated the following:

- Visual Inspection
- Dimensional Measurements
- Outer tube rotation
- Device/Scope/Camera Clearance
- Tissue trap is removable
- Inflow spike to tubing tensile strength
- ¼" Luer to tubing tensile strength
- Trigger force test
- Outer tube/blade tensile test
- Drain tube to connector tensile test
- Tissue trap volume
- Cutting Rate
- Fluid Usage
- Tissue Trap Efficiency

All testing met the acceptance criteria.

Usability and human factors were addressed through Voice of Customer (VOC) studies and design validation. Testing was done to demonstrate that the MyoSure MANUAL Tissue Removal Device meets user needs and intended use. The testing included 15 physicians with a range of experience. Testing was conducted with a simulated uterine model that included pieces of chicken breast to simulate the target tissue. Design verification, validation testing and usability testing confirmed that the device performs as intended.

**CONCLUSION**

Based on the intended use, descriptive information and performance provided in this submission, the MyoSure MANUAL Tissue Removal Device has been shown to be substantially equivalent to the predicate MyoSure LITE Tissue Removal Device.